

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE  
 (REV. 7-2005)

TRANSMITTAL LETTER TO THE UNITED STATES  
 DESIGNATED/ELECTED OFFICE (DO/EO/US)  
 CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER

RLL-268.1US

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/525,438 **10/525438**

INTERNATIONAL APPLICATION NO.  
 PCT/IB2002/003740

INTERNATIONAL FILING DATE  
 09/12/2002

PRIORITY DATE CLAIMED  
 08/26/2002

TITLE OF INVENTION

AZOLE DERIVATIVES AS ANTIFUNGAL AGENTS

APPLICANT(S) FOR DO/EO/US

SALMAN et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. **EV 483376138US**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO (if known, see 37 CFR 1.5) <b>10/525,438</b>	INTERNATIONAL APPLICATION NO. <b>PCT/IB2002/003740</b>	ATTORNEY'S DOCKET NUMBER <b>RLL-268.1US</b>
---------------------------------------------------------------------	-----------------------------------------------------------	------------------------------------------------

23. Other items or information:  
**Certificate of Express Mailing**  
**Information Disclosure Citation w/refs.**  
**Return Postcard**

	CALCULATIONS	PTO USE												
The following fees have been submitted:														
24. <input type="checkbox"/> Basic national fee . . . . . \$300	\$ 0.00													
25. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article All other situations. . . . . \$200	\$ 0.00													
26. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). . . \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. . . . . \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. . . . . \$400 All other situations. . . . . \$500	\$ 0.00													
<b>TOTAL OF 24, 25 and 26 =</b>	\$ 0.00													
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.														
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Total Sheets</th> <th>Extra Sheets</th> <th>Number of each additional 50 or fraction thereof (round up to a whole)</th> <th>RATE</th> </tr> </thead> <tbody> <tr> <td>- 100 =</td> <td>0 /50 =</td> <td>0</td> <td>x \$250.00</td> </tr> </tbody> </table>	Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE	- 100 =	0 /50 =	0	x \$250.00	\$ 0.00					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE											
- 100 =	0 /50 =	0	x \$250.00											
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).														
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>CLAIMS</th> <th>NUMBER FILED</th> <th>NUMBER EXTRA</th> <th>RATE</th> </tr> </thead> <tbody> <tr> <td>Total claims</td> <td>- 20 =</td> <td>0</td> <td>x \$50.00</td> </tr> <tr> <td>Independent claims</td> <td>- 3 =</td> <td>0</td> <td>x \$200.00</td> </tr> </tbody> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total claims	- 20 =	0	x \$50.00	Independent claims	- 3 =	0	x \$200.00	\$ 0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE											
Total claims	- 20 =	0	x \$50.00											
Independent claims	- 3 =	0	x \$200.00											
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00	\$ 0.00													
<b>TOTAL OF ABOVE CALCULATIONS =</b>	\$ 0.00													
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.														
<b>SUBTOTAL =</b>	\$ 0.00													
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).														
<b>TOTAL NATIONAL FEE =</b>	\$ 0.00													
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +	\$ 0.00													
<b>TOTAL FEES ENCLOSED =</b>	\$ 0.00													
	Amount to be	\$												
	Amount to be	\$												

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0912. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Jayadeep R. Deshmukh  
Reg. No. 34,507  
Customer No. 026815

William D. Hare  
SIGNATURE

**William D. Hare**

NAME

**44,739**

REGISTRATION NUMBER

**7 March 2006**

DATE

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
**(Under 37 CFR 1.97(b) or 1.97(c))**

Docket No.  
**RLL-268.1US**

In Re Application Of: **SALMAN et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/525,438	9/12/2002	TBA	026815	TBA	

Title:  
**AZOLE DERIVATIVES AS ANTIFUNGAL AGENTS**

Address to:  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:
- ☐ the statement specified in 37 CFR 1.97(e);
- OR**
- ☐ the fee set forth in 37 CFR 1.17(p).

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
RLL-268.1US

In Re Application of: **SALMAN et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/525,438	9/12/2002	TBA	026815	TBA	

Title:  
**AZOLE DERIVATIVES AS ANTIFUNGAL AGENTS**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. 50-0912  
as described below.
- ☐ Charge the amount of \_\_\_\_\_
- ☐ Credit any overpayment.
- ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

**Certificate of Transmission by Facsimile\***

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fa
_____ (Date)
_____ Signature
_____ Typed or Printed Name of Person Signing Certificate

**Certificate of Mailing by First Class Mail**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on
_____ (Date)
_____ Signature of Person Mailing Correspondence
_____ Typed or Printed Name of Person Mailing Certificate

**\*This certificate may only be used if paying by deposit account.**

  
Signature

Dated: **March 7, 2006**

**William D. Hare, Esq.**  
Reg. No. 44,739  
Ranbaxy Inc.  
600 College Road East, Suite 2100  
Princeton, New Jersey 08540  
Tel.: 609 720-5334  
Fax: 609 514-9779

cc:

<b>INFORMATION DISCLOSURE CITATION</b>	Docket No.: RLL-268.1US	Serial No.: 10/525,438
	Applicants: SALMAN <i>et al.</i>	
	Filed: 2/23/2005	Group:

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	6,133,485	10/17/2000	Singh <i>et al.</i>	568	700	

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES   NO
	B1	EP 0 097 469	1/4/1984	EPO	C07D	249/08	
	B2	EP 0 567 982	11/3/1993	EPO	C07D	249/12	
	B3	EP 0 967 210	12/29/1999	EPO	C07D	249/08	
	B4	WO 96/39394	12/12/1996	PCT	C07D	249/12	Abstract
	B5	WO 01/66551	9/13/2001	PCT	C07D	521/00	
	B6	WO 02/51408	7/4/2002	PCT	A61K	31/41	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	C1	Fromtling, "Overview of Medically Important Antifungal Azole Derivatives", <i>Clinical Microbiology Reviews</i> , <u>1</u> (2):187-217 (1988)
	C2	Greenspan, "Treatment of oropharyngeal candidiasis in HIV-positive patients", <i>The Journal of the American Academy of Dermatology</i> , <u>31</u> :S51-S55 (1994)
	C3	Georgopapadakou and Walsh, "Antifungal Agents: Chemotherapeutic Targets and Immunologic Strategies", <i>Antimicrobial Agents and Chemotherapy</i> , <u>40</u> (2):279-291 (1996)
	C4	Fung-Tomc et al, "Recent developments in pradimicin-benanomicin and triazole antibiotics", <i>Expert Opinion on Investigational Drugs</i> , <u>6</u> (2):129-145 (1997)
	C5	Kauffman and Carver, "Antifungal Agents in the 1990s", <i>Drugs</i> , <u>53</u> (4):539-549 (1997)
	C6	Koltin and Hitchcock, "The search for new triazole antifungal agents", <i>Current Opinion in Chemical Biology</i> , <u>1</u> :176-182 (1997)
DOCUMENT TO FOLLOW	C7	<u>Antifungal Agents</u> , "Principles and practice of infectious diseases", 4 <sup>th</sup> ed. pgs 401-410, G.L. Mandel, J.E. Bennett and R.Dolin (ed.), Churchill Livingstone, Inc. New York, N.Y

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

**INFORMATION DISCLOSURE CITATION**

Docket No.: RLL-268.1US

Serial No.: 10/525,438

Applicants: SALMAN *et al.*

Filed: 2/23/2005

Group:

C8

Nguyen et al., "The Changing Face of Candidemia: Emergence of Non-Candida albicans Species and Antifungal Resistance", *The American Journal of Medicine*, 100(6):617-623 (1996)

C9

Sheehan et al., "Current and Emerging Azole Antifungal Agents", *Clinical Microbiology Reviews*, 12(1):40-79 (1999)

C10

Perfect et al., "In Vitro and In Vivo Efficacies of the Azole SCH56592 against *Cryptococcus neoformans*", *Antimicrobial Agents and Chemotherapy*, 40(8):1910-1913 (1996)

C11

36th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 1996, New Orleans. Abst. F74, F87-102

C12

Naito et al., "ER-34346 Triazole Antifungal", *Drugs of the Future*, 21(1):20-24 (1996)

C13

Kitazaki et al., "Optically Active Antifungal Azoles. VI.1) Synthesis and Antifungal Activity of *N*-[(1*R*,2*R*)-2-(2,4-Difluorophenyl)-2-hydroxy-1-methyl-3-(1*H*-1,2,4-triazol-1-yl)propyl]-*N'*-(4-substituted phenyl)-3(2*H*,4*H*-1,2,4-triazolones and 5(1*H*,4*H*)-tetrazolones", *Chemical and Pharmaceutical Bulletin*, 44(2):314-327 (1996)

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: SALMAN *et al.*  
U.S. Application No.: 10/525,438  
International Application No.: PCT/IB2002/003740  
International Filing Date: 09/12/2002  
Title: AZOLE DERIVATIVES AS ANTIFUNGAL AGENTS

**CERTIFICATE OF EXPRESS MAILING**

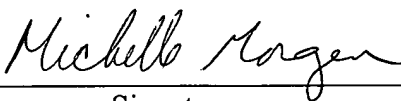
I hereby certify that the following correspondence:

- Transmittal Letter to the US/DO/EO Concerning a Filing Under 35 USC 371
- Information Disclosure Citation w/references
- Transmittal of Information Disclosure Statement
- Postcard

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on 7 March 2006.

Michelle Morgan

Name of Person Mailing Correspondence



Signature

EV 483376138 US

"Express Mail" Mailing Label Number